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Related Change Request (CR) #: 7137

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Related CR Transmittal #: R127NCD and

Implementation Date: November 10, 2010

Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) for Myelodysplastic Syndrome (MDS)

Note: This article was revised on July 27, 2016, to add a reference to MLN Matters® Article [MM9620](#) to alert providers that CMS has expanded national coverage of allogeneic HSCT in an approve clinical study to also cover multiple myeloma, myelofibrosis, and Sickle Cell Disease. All other information remains unchanged.

Provider Types Affected

This article is for physicians, providers, and hospitals billing Medicare contractors (carriers, Fiscal Intermediaries (FIs), and Medicare Administrative Contractors (A/B MACs)) for providing Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) services to Medicare beneficiaries with Myelodysplastic Syndrome (MDS).

What You Need to Know

Change Request (CR) 7137, from which this article is taken, announces (through a National Coverage Determination (NCD)) that, effective for claims with dates of service on and after August 4, 2010, Medicare will cover the use of Allogeneic HSCT for treatment of MDS under section 1862(a)(1)(E) of The Social Security Act (the Act) **ONLY** if provided in the context of a Medicare-approved clinical study meeting specific criteria under Coverage with Evidence Development (CED). The Centers for Medicare & Medicaid Services (CMS), pursuant to the NCD process, has determined that the evidence does not demonstrate the use of Allogeneic HSCT improves health outcomes in Medicare beneficiaries with MDS, is not reasonable and necessary under section 1862(a)(1)(A) of the Act, and is therefore not covered by Medicare **EXCEPT** when provided in a Medicare-approved clinical study.

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Background

MDS refers to a group of diverse blood disorders in which the bone marrow does not produce enough healthy, functioning blood cells. These blood disorders are varied with regard to clinical characteristics, cytologic and pathologic features, and cytogenetics. The abnormal production of blood cells in the bone marrow leads to low blood cell counts, referred to as cytopenias, which are a hallmark feature of MDS along with a dysplastic and hypercellular-appearing bone marrow.

On November 10, 2009, CMS accepted a formal request from several bone marrow and cancer organizations and societies, asking for national coverage of Allogeneic HSCT for Medicare beneficiaries "who would either be at high risk for progression to leukemia or be at risk for MDS complications that place them at high risk for death or prevent the future possibility of a transplant."

Coding Information

CR 7137 describes, effective for claims with dates of service on and after August 4, 2010, the codes that you will need to supply on your claims for the use of HCST for MDS to help your FI, carrier, or A/B MAC, determine if the treatment was provided pursuant to a Medicare-approved clinical study under CED using existing clinical trial coding conventions described in MLN Matters® article MM5790, *Use of an 8-Digit Registry Number on Clinical Trial Claims*, released on January 18, 2008, (found at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM5790.pdf> on the CMS website).

Effective for claims with discharge dates on or after August 4, 2010, your Inpatient claims (Type of Bill (TOB) 11X) for HSCT for the treatment of MDS in a clinical study must contain:

- ICD-9 diagnosis code V70.7;
- Condition Code 30;
- HSCT-ICD-9-CM procedure codes 41.02, 41.03, 41.05, or 41.08; and
- MDSICD-9-CM diagnosis code 238.75.

Outpatient hospital claims (TOB13X) for dates of service on or after August 4, 2010, for HSCT for the treatment of MDS in a clinical study must contain:

- HSCT CPT code 38240;
- MDS ICD-9-CM diagnosis code 238.75;
- Clinical Trial ICD-9-CM diagnosis code V70.7; and
- Clinical Trial Procedure Code Modifier Q0.

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Practitioner claims for dates of service on or after August 4, 2010, billed by a Method II Critical Access Hospital on TOB 85X with Revenue Code 96X, 97X, or 98X, for HSCT for the treatment of MDS must contain:

- HSCT CPT code 38240;
- MDS ICD-9-CM diagnosis code 238.75;
- Clinical Trial ICD-9-CM diagnosis code V70.7; and
- Clinical Trial Procedure Code Modifier Q0.

Professional claims for HSCT for the treatment of MDS for dates of service on or after August 4, 2010, for HSCT for the treatment of MDS must contain:

- HSCT CPT code 38240;
- MDS ICD-9-CM diagnosis code 238.75;
- Clinical Trial ICD-9-CM diagnosis code V70.7;
- Clinical Trial Procedure Code Modifier Q0; and
- Place of Service Code 21 or 22.

Note that the 8-digit clinical trial number may also appear on the claim, at the discretion of the provider (along with Value Code D4 for inpatient claims).

Medicare contractors will use the following messages if they deny claims for HSCT for the treatment of MDS that do not contain all of the required coding requirements mentioned above:

- Claim Adjustment Reason Code (CARC) 50 - These are non-covered services because this is not deemed a 'medical necessity' by the payer. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.
- Remittance Advice Remark Code (RARC) N386 - This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx>. If you do not have web access, you may contact the contractor to request a copy of the NCD.
- Group Code - Patient Responsibility (PR) if an Advance Beneficiary Notice (ABN) or Hospital Issued Notice of Non-coverage (HINN) given to the beneficiary, otherwise Contractual Obligation (CO).

Finally, you should be aware that for claims with dates of service between August 4, 2010, and the implementation date of CR 7137, your contractor will perform necessary adjustments only when you bring affected claims to their attention.

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Additional Information

More details are available in the official notice to your Medicare contractor, CR 7137, which was issued in two transmittals. The first transmittal updated the “Medicare NCD Manual”, and it is available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R127NCD.pdf> on the CMS website. The second transmittal updated the “Medicare Claims Processing Manual” and it is available at <http://www.cms.gov/Transmittals/downloads/R2062CP.pdf> on the CMS website. You can also review the entire decision memorandum regarding this NCD at <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx> on the CMS website. Appendix D of that memorandum contains instructions for submission of applications for protocols to address CED as required by an NCD.

If you have questions, please contact your carrier, FI, or A/B MAC, at their toll-free number, which may be found at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html> on the CMS Website.

Document History

Date	Description
July 27, 2016	The article was revised to add a reference to MLN Matters® Article MM9620 to alert providers that CMS has expanded national coverage of allogeneic HSCT in an approve clinical study to also cover multiple myeloma, myelofibrosis, and Sickle Cell Disease.
October 14, 2010	Initial article released

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